



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,583	09/09/2003	Jae-Gahb Park	DE-1504	7790
<div>7590      02/26/2007 David A. Einhorn, Esq. Anderson Kill &amp; Olick, P.C. 1251 Avenue of the Americas New York, NY 10020</div>			<div>EXAMINER SALMON, KATHERINE D</div>	
			<div>ART UNIT 1634</div>	<div>PAPER NUMBER</div>
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/659,583	<b>Applicant(s)</b> PARK ET AL.	
	<b>Examiner</b> Katherine Salmon	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This action is in response to the papers filed 11/21/2006. Currently, Claims 1 and 7-20 are pending. Claims 7-20 have been withdrawn as being drawn to a nonelected invention.
2. The following rejections to claims 1 are newly applied.
3. This action is NONFINAL.

### ***Priority***

4. Priority to foreign application Republic of Korea 2003-0000987 (01/08/2003) under 35 U.S.C. 119(a)-(d) has been granted because a translation of the foreign application was provided on 11/21/2006. Therefore the filing date of the US application 01/08/2003 will be used.

### **Withdrawn Objections**

5. The objection to the drawings made in Section 5 of the previous office action is moot in view of the amendment to delete Figure 3.

### **Withdrawn Rejections**

6. The rejection of the claims under 35 USC 102(a) made in Section 6 of the previous office action is moot in view of the submission of the translated priority document.

Art Unit: 1634

7. The rejection of the claims under 35 USC 102(b) made in Section 7 and 8 of the previous office action is moot in view of the amendments to the claims.

***Newly Applied Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham et al. (American Journal of Pathology March 2001 Vol. 158 p. 1073) in view of Udatsu et al. (Pediatric Surg Int. 2001 Vol. 17 p. 508), Fujimori et al. (Cancer Research 2001 Vol.

Art Unit: 1634

61 p. 6656), Hacia et al. (Genome Research 1998, Vol. 8 p. 1245) and GenBank Accession Number Z19054 (NCBI website December 20, 1999).

The rejected claim is drawn to a microchip which comprises a plurality of oligonucleotides fixed on the surface of a solid matrix, wherein the oligonucleotides detect B-catenin mutations. The probes of SEQ ID NO. 1 to 121 represent potential missense mutations and deletion mutations of codons 29, 31-35, 37-38, 41, 45, and 48 of the B-catenin gene.

Abraham et al., Udatsu et al, and Fujimori et al. teach screening methods to detect the specific codons and association of the codons to cancer.

Abraham et al. teaches detection of B-catenin mutations to detect tumors (Abstract). Abraham et al. teaches the detection of mutations in Codon 33, 34, 35, and 37 (Table 1 p. 1076). Further Abraham et al. teaches the deletion of codons 28-40 is associated with detection of tumors (Table 1 p. 1076).

Udatsu et al. teaches the detection of missense mutations associated with neoplasm (Abstract). Udatsu et al. teaches that missense mutations at codons 32, 34, or 37 can be used to detect tumourigenesis of hepatoblatoma (abstract). Udatsu et al. teaches an SNP change in codon 31 was also detected (p. 511 2<sup>nd</sup> column 1<sup>st</sup> full paragraph).

Fujimori et al. teaches the detection of mutations in exon 3 of B-catenin and association with gastrointestinal carcinoid tumors (Abstract). Fujimori et al. teaches the detection of codons 37-38 and 48 (Table 1 p. 6658). Fujimori et al. further analyzes exon 3 at codons 29, 33, 41 and 45 because these amino acids can be directly

Art Unit: 1634

phosphorylated and therefore changes in these amino acids could protect B-catenin from phosphorylation (p. 6657 2<sup>nd</sup> column 2<sup>nd</sup> paragraph).

Therefore, the art as represented by Abrahams et al., Udatsu et al., and Fujimori et al., teaches that these codon regions are important to the expression of B-catenin and that mutations in these codon regions have been associated with cancer.

However, Abrahams et al., Udatsu et al., and Fujimori et al. do not teach an oligonucleotide microchip having oligonucleotides fixed on the surface of a solid matrix.

At the time the invention was made, the sequence of the beta catenin gene was known, and disclosed, for example in the GenBank record. For example, codon 29 is nucleotides 276-296 of the sequence of record, and codon 41 is nucleotides 312-332. Hacia et al. teaches an oligonucleotide array, which teach strategies for mutational analysis of the ATM gene using oligonucleotide arrays. Hacia et al. teach microarrays that have thereupon oligonucleotides to detect all possible variations in the ATM coding sequence using probes that are 25 nucleotides in length (p. 1246 2<sup>nd</sup> column and Abstract).

Given all of these teachings, it would have been prima facie obvious to one of ordinary skill in the art to have produces a microarray for the detection of mutations in the B-catenin gene. In view of the teachings of Abrahams et al., Udatsu et al., and Fujimori et al. in view of Hacia et al., it would have been prima facie obvious to have produces a microarray that interrogated all possible variations in the B-catenin coding sequence in order to assay for additional variations in the coding sequence that might be related to any carcinoma using as a basis the sequence given by the GenBank

Art Unit: 1634

record. Such a microarray would have comprised each of the sequences given in SEQ ID NO: 1-SEQ ID NO: 121 since these are all fewer than 25 nucleotides, and Hacia et al. teach using 25 nucleotide oligonucleotides with the variation in the center of the probe. Alternatively, it would have been obvious to have made only probes to the codons specifically taught by Abrahams et al., Udatsu et al., and Fujimori et al. as being known mutational hot spots within the B-catenin gene so as to have focused the search for additional mutations to codons that were known to be relevant to carcinoma. One would have been motivated to make these arrays by the teaching of Abrahams et al., Udatsu et al., and Fujimori et al. who specifically exemplify screening samples for mutations in the B-catenin gene, and by the teachings of Hacia et al. who teaches that microarray based methods have an advantage over traditional electrophoresis based methods (such as single stranded conformation analysis) which add complications to scale-up and automation (p. 1246). Furthermore, Hacia et al. that "Because DNA chip technology has the potential to analyze virtually any gene for heterozygous sequence variations, the hybridization-based strategies used in this study should be applicable to mutational analysis in many other systems (p. 1255). Therefore, given these teachings, the claimed invention is prima facie obvious.

### ***Conclusion***


10. No Claim is allowed.


Art Unit: 1634

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Katherine Salmon  
Examiner  
Art Unit 1634

  
CARLA J. MYERS  
PRIMARY EXAMINER